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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,843	07/14/2000	Peter Nash	C150.12.3B	6411

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EXAMINER

HUYNH, PHUONG N

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/02/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,843

Applicant(s)

NASH ET AL.

Examiner

" Neon" Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/12/01, 7/26/01, 9/18/01 and 10/18/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11 and 14-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11 and 14-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 10-11 and 14-32 are pending.
2. In view of the amendments filed 6/12/01, 9/18/01 and 10/18/01, only the following rejections remain.
3. Claims 10-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) in view of Tokoro *et al*. (US Pat No. 5,080,895, IDS; See entire document) for the same reasons set forth in Paper No 6.

Applicants' arguments filed 10/18/01 have been fully considered but are not found persuasive.

Applicants' position is that there is no information in Krause *et al* of a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogens such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilium* by inhibiting the said immunogen to adhere to the rumen or intestinal tracts of food animals and reduces the ability of the immunogen to multiply, (2) There is no disclosure in Tokoro *et al* of any method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilium* in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogens from adhering to the rumen or intestinal tracts of food animals to reduce the ability of the said immunogens to multiply, (3) there is no suggestion producing P, CS and CA antigens and distributing antibody-containing contents to these antigens to animal feed or water and supplying this animal feed or water to feed animals to promote growth of these animals.

However, Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

The claimed invention in claim 10 differs from the reference only by the recitation promoting the growth of food animals by decreasing the waste of dietary protein caused by the

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presence of colony-forming protein-wasting immunogens in rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, said method comprising (A) inoculating female birds, in or about to reach their egg laying age, with the particular targeted protein-wasting immunogen; (B) after a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, harvesting the eggs laid by the birds, (C) separating the antibody-containing contents of said eggs from the shell; (D) drying said separated egg antibody material; (E) distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water and (F) supplying the resulting antibody-containing animal feed or water to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tract of the animal.

The claimed invention in claim 14 differs from the reference only by the recitation of said Protein wasting immunogen is P antigen from *P. anaerobius*.

The claimed invention in claim 15 differs from the reference only by the recitation of said Protein wasting immunogen is CS antigen from *C. sticklandii*.

The claimed invention in claim 16 differs from the reference only by the recitation of said Protein wasting immunogen is CA antigen from *C. aminophilum*.

Tokoro *et al.* teach a method of promoting the growth of food animals by preventing diarrhea in livestock by adding bird antibody (IgY) against various bacterial antigens (immunogens) such as *E. Coli* as a feed additive wherein the inherent function of IgY is to inhibit *E coli* from adhering to the rumen or intestinal tracts of the livestock and reduce the ability of the ability of the *E Coli* to multiply. The reference method comprises inoculating female bird with the targeted immunogen such as *E Coli*, after a period of time sufficient to permit the production of bird antibody IgY to the *E. Coli*, harvesting the IgY antibody from the shells, drying the separated egg antibody IgY material, mixing the resulting dry egg antibody IgY throughout the animal feed or water and supplying the resulting antibody-containing animal feed to livestock (See column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31 in particular). Tokoro *et al* further teach the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the *E coli* as taught by Tokoro with the immunogen such as

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Peptostreptococcus anaerobius, *Closteridium sticklandii*, and *Clostridium aminophilum* as taught by Krause *et al* for a method of promoting the growth of food animal such as livestock as taught by Tokoro *et al*. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document) and adding antibiotic such as monensin as a ruminant feed additive decreases only the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilum* in livestock. Tokoro *et al* teach a method of promoting the growth of food animals by preventing diarrhea in livestock by adding bird antibody (IgY) against *E coli* as a feed additive and the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

4. The following new ground of rejection is necessitated by amendment filed 10/18/01.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 17-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) and Tokoro *et al*. (US Pat No. 5,080,895, PTO 1449) as applied to claims 10-11 and 14-16 above and further in view of US Pat 6,086,878 (Jul 2000, PTO 892) and US Pat No. 4,166,867 (Sept 1979, PTO 892).

The teachings of Krause *et al* and Tokoro *et al* have been discussed supra.

The claimed invention in claims 17, 19, 21, 23, 25, 27, 29 and 31 differs from the reference only by the recitation of drying said antibody-containing contents by coating the dry feed carrier material with said antibody-containing contents, distributing said carrier material coated with said antibody-containing contents in animal feed or water and supplying the carrier material coated with said antibody-containing contents and animal feed or water to substantially prevent adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claims 18, 20, 22 and 24, 26, 28, 30 and 32 differs from the reference only by the recitation of said dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat the animal feed with hyperimmunized spray-dried egg powder as taught by the '878 patent with the dry feed as taught by the '867 patent using the antibody-containing content (IgY) as taught by Tokoro *et al* directed against the immunogen such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* as taught by Krause *et al*. From the combined teachings of the references, it is apparent that one of

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ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material along as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document) and adding antibiotic such as monensin as a ruminant feed additive decreases only the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilum* in livestock. Tokoro *et al* teach a method of promoting the growth of food animals by preventing diarrhea in livestock by adding bird antibody (IgY) against E coli as a feed additive and the method of making bird antibody to any bacteria of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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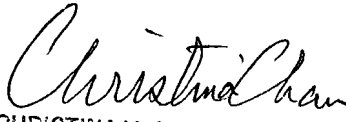
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
11. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

December 31, 2001


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GROUP 1800-1644